

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESAL PRICE)	
LITIGATION)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti Saris
)	
<i>United States of America, ex rel. Ven-a-Care</i>)	
<i>of the Florida Keys, Inc., v. Abbott</i>)	
<i>Laboratories, Inc., and Hospira, Inc.</i>)	
CIVIL ACTION NO. 06-11337-PBS)	

**UNITED STATES' AND RELATOR'S MEMORANDUM
IN SUPPORT OF THEIR MOTION FOR A PROTECTIVE ORDER**

I. Introduction

The United States and Relator hereby move this Court, pursuant to the Court's Order dated August 25, 2006 (Dkt. No. 3031), and the Court's authority under Rule 26(c)(7) of the Federal Rules of Civil Procedure, to enter the proposed Protective Order (Ex. 1), governing the use and dissemination of all confidential information by any party or third party, which differs from the Protective Order currently in place ("AWP MDL Protective Order," Dkt. No. 276).¹ We further request that the proposed Protective Order apply not only to the case captioned above, but to any other case that is transferred to *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS ("AWP MDL"), for coordinated or consolidated pretrial proceedings, in which the United States is a party. As

¹Generally, the United States and Relator have attempted to adopt as much of the AWP MDL Protective Order currently in place. See Protective Order (Dkt. No. 276). However, for efficiency and to minimize confusion that may result from entering an addendum of amendments to the current Protective Order (Dkt. No. 276), the United States and Relator have drafted and hereby propose that the Court enter a separate Protective Order, found at Ex. 1.

explained further below, the United States has become a party for the first time to this AWP MDL. We need to ensure that the case is litigated in the public eye to the maximum extent possible and that an order is drafted to accomplish this while also protecting the legitimate interests of defendants. Thus, the proposed Protective Order will serve the purposes it was intended to serve, and will address the unique concerns of the United States, including its law enforcement interests and its interests in ensuring open and public civil discovery proceedings.

II. Legal Standard

Protective orders regarding the confidentiality of discovery materials are governed by Rule 26(c) of the Federal Rules of Civil Procedure ("Federal Rules"), which states, among other things, that the court "may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" Rule 26(c)(7) of the Federal Rules states that the court may order "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way."

III. Purpose Served by a Protective Order in Civil Discovery

The United States and Relator propose their Protective Order in order to achieve the purposes served by a protective order in civil discovery, and to be consistent with terms the United States has negotiated in other similar cases it has litigated. The overarching purpose of a protective order governing trade secrets and other confidential research, development, or commercial information is to prevent unauthorized disclosure of the materials to competitors and others, not to prevent the opposing party from accessing and using the discovery to prepare its case. Fed. R. Civ. P. 26(c)(7). The United States' and Relator's proposed Protective Order is

oriented toward the former, and takes into account the United States' unique interests as a party to this litigation at this time. The United States and Relator were not parties to this case at the time the Court entered the stipulated Protective Order on December 13, 2002 (Dkt. No. 276).²

In determining whether to enter a protective order, a critical consideration is whether under the terms of the order, the discovering party will be able to prosecute its case efficiently and fairly.

In fashioning the order, it is important to balance the movants' legitimate concerns about confidentiality against the needs of the litigation, individual privacy, or the commercial value of the information while making it available for legitimate litigation use. Protecting *only* material for which *a clear and significant need for confidentiality has been shown* will reduce the burdensomeness of the order and render it less vulnerable to later challenge.

Manual for Complex Litigation (Fourth), §11.432, at 66-67 (2004) (emphasis supplied); *see also John Doe I-VI v. Yogi*, 110 F.R.D. 629, 633-34 (D.D.C. 1986) (refusing to enter protective order “that would interfere with plaintiffs’ ability to communicate with counsel, experts, or each other in preparation for trial”) (citing *Doe v. District of Columbia*, 697 F.2d 1115, 1119 (D.C. Cir. 1983) (district court must “be careful to grant [an order that restricts dissemination to the public of discovered information] only when essential to shield a party from significant harm or to protect an important public interest”); *In re Independent Service Organizations Antitrust*

²The parties in this case engaged in numerous good faith discussions, including communications on this subject as recently as September 1, 2006, and we believe had come close to agreed-upon provisions for a Protective Order applicable to this case. However, it appears that once the Court entered its Aug. 25 Order (Dkt. No. 3031), the government heard no further comments from Abbott with respect to the proposed Protective Order. We believe that the terms in the proposed Protective Order are reasonable, and that Abbott may well agree with most of them.

Litigation, 162 F.R.D. 355, 356 (D. Kan. 1995) (noting that “if relevancy and sufficient need are established, the trade secrets should generally be disclosed, unless they are privileged, or the subpoenas are unreasonable, oppressive, annoying, or embarrassing.”) (internal quotation marks omitted).

Moreover, civil discovery is to be liberally allowed and “must take place in the (sic) public unless compelling reasons exist for denying the public access to the proceedings.” *Wilk, et al. v. Am. Medical Assoc., et al.*, 635 F.2d 1295, 1299 (7th Cir. 1980); *see also, Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119 (2d. Cir. 2006) (“The right of public access to judicial documents is firmly rooted in our nation’s history . . . Without [public] monitoring, moreover, the public could have no confidence in the conscientiousness, reasonableness, or honesty of judicial proceedings. Such monitoring is not possible without access to testimony and documents that are used in the performance of Article III functions.”); *San Jose Mercury News v. U.S. District Court – Northern District (San Jose)*, 187 F.3d 1096, 1102–03 (9th Cir. 1999) (“we have expressly recognized that the federal common-law right of [public] access extends to pretrial documents filed in civil cases . . . it is well established that the fruits of pretrial discovery are, in the absence of a court order to the contrary, presumptively public.”) (internal citations omitted); *Krynicky and Lopachic v. Falk II*, 983 F.2d 74, 75 (7th Cir. 1992) (“Judicial proceedings in the United States are open to the public – in criminal cases by constitutional command, in civil cases by force of tradition . . . Judges deliberate in private but issue public decisions after public arguments based on public records. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat; this requires rigorous justification.”). In deciding what protective order provisions would be

appropriate to protect the Coca-Cola formula in litigation, a federal court aptly noted that “[n]othing is sacred in civil litigation.” *Coca-Cola Bottling Company of Shreveport, Inc. V. Coca-Cola Co.*, 107 F.R.D. 288, 290 (D. Del. 1985). The presumption in favor of open proceedings is all the more compelling in this case, where the United States is seeking recovery of public funds. Thus, the United States and Relator ask that this Court enter their proposed Protective Order which is fair and reasonable to the parties, serves the public’s interest to a right of access, protects the interests of the United States in its law enforcement capacity, and adequately prevents the unauthorized disclosure of confidential information and trade secrets to Abbott’s and other defendants’ competitors.

IV. What Constitutes Confidential Information

The United States and Relator propose that the Court adopt the express language of Rule 26(c)(7) of the Federal Rules of Civil Procedure (“Federal Rules”), which defines the information that is entitled to protection from a defendant’s competitors. *See* proposed Protective Order, Ex. 1, ¶ 4. We further ask that the Court expressly adopt the definition of “Trade Secrets” as that term is defined under the Uniform Trade Secrets Act, § 1(4):

Information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (a) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

See proposed Protective Order, Ex. 1, ¶ 4. The current AWP MDL Protective Order could be construed to include virtually any business document created by Defendant. It allows for the designation of not only material protected by Rule 26(c)(7) of the Federal Rules, but also all

“proprietary or commercially sensitive information” and “personal financial information.”

Neither of those terms, which are broader than the protections afforded by Rule 26(c)(7), are defined in the Protective Order, allowing defendants to define it for themselves. *See* AWP MDL Protective Order, Dkt. No. 276, ¶ 3. Of even greater concern is paragraph 5 of the AWP MDL Protective Order, which immunizes against disclosure, all current and past (to the extent they reflect on current) “methods, procedures, and processes relating to the pricing of pharmaceuticals...marketing plans and methods...business planning and financial information”; and all “past or current company personnel or employee information.” On their face these terms are overly broad under Federal Rule 26(c)(7), and all of them are left to a defendant’s unilateral interpretation of the meaning of these terms.

The courts have not given trade secrets automatic and complete immunity against disclosure, but have in each case weighed their claim to privacy against the need for disclosure. Frequently, they have been afforded a limited protection. *See, e.g., Covey Oil Co. v. Continental Oil Co.*, 340 F.2d 993 (10th Cir. 1965); *Julius M. Ames Co. v. Bostitch, Inc.*, 235 F. Supp. 856 (S.D.N.Y. 1964).

Fed. R. Civ. P. 26(c), 1970 Advisory Committee notes.

It is unclear as to the volume of documents that Abbott expects to designate as confidential in this case, but the United States has expressed to Abbott its serious concern that the number of documents Abbott intends to designate may be significant in number as a result of improper over-designations. The United States has conducted a random review of the approximately 250,000 pages of materials that Abbott recently produced as its complete set of Federal Rule 26(a)(1) initial disclosures in this case. Every page reviewed so far contained a

“highly confidential” or “confidential” designation by Abbott.³ In fact, nearly blank pages were included among the materials that Abbott designated as “highly confidential materials.”⁴ Abbott also designated as “confidential” each of the more than 760 pages of Abbott's transmission of its data to price reporting reference compendia, including Redbook, First DataBank, and Medispan, the companies that published the very information that Abbott transmitted to them. *See* Letter to Abbott Counsel, Ex. 7, 1-2.

The United States has proposed a fair and reasonable procedure to challenge excessive and improper designations that appropriately places the burden upon the party designating the confidential information to file a motion for a protective order with the Court, demonstrating that good cause exists to treat the challenged information as protected subject to the terms of the Protective Order. *See* proposed Protective Order, Ex. 1, ¶ 15. This procedure comports with the Federal Rules. *See* Fed R. Civ. P. 26(c) (burden rests with party seeking protection).

V. The United States Has the Right to Share Discovery With the States

Absent from the AWP MDL Protective Order is the ability of the United States to share information it receives in discovery with the states. We request that the Court adopt the

³In a letter to Abbott counsel from Assistant United States Attorney, Mark Lavine, dated September 8, 2006, Mr. Lavine wrote, “[E]very document I have seen to date is designated as confidential and none seem to warrant such a designation. For example, ABT-DOJ 0190431 through ABT-DOJ 0191192 consist solely of documents transmitted by Abbott employee Jerrie Cicerale to either Redbook, First DataBank or Medispan so that those companies could then publish the information . . . [such over-designations] will hamper our review of the documents, contravenes one of the key purposes of the MDL process and need to be promptly corrected.” Letter to Abbott Counsel, Ex. 7, 1-2.

⁴The United States cannot provide as examples in this motion the nearly blank pages of documents that Abbott designated as confidential because they would need to be filed under seal under the terms of either protective order.

proposed Protective Order which includes a provision for such sharing. *See* proposed Protective Order, Ex. 1, ¶ 13(j). In its law enforcement capacity, the United States should be permitted to share discovery with our law enforcement partners, including the state Attorneys General and others who work with them, that have active investigations of pricing issues similar to those alleged in the Complaint.

Permitting the United States to share discovery with the states is consistent with the statutory scheme of Medicaid, a joint federal-state program. Because the costs of the Medicaid program are paid jointly by both the federal and state governments, both governments typically pursue a common purpose in preventing fraud. *Cf. Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 666 (2003); *PhRMA v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002) (describing Medicaid as a "cooperative state-federal program"). States have long played a critical role in investigating and prosecuting Medicaid fraud. *See* 42 U.S.C. § 1396b(q)(3) (requiring states to maintain a Medicaid Fraud Control Unit (MFCU) to investigate fraud in connection with Medicaid state plan); 42 U.S.C. § 1396a(a)(61) (requiring state plan to provide for operation of a Medicaid fraud and abuse control unit); 42 U.S.C. § 1396a(a)(25) (requiring states to "take all reasonable measures to ascertain the legal liability of third parties" and to pursue reimbursement). Consistent with this statutory scheme, if documents produced by a defendant contain evidence of fraud against a particular state Medicaid program, the federal government must have the right to share such information with the relevant state authorities.⁵

⁵Further, Congress recently enacted a provision in the Deficit Reduction Act of 2005 encouraging states to investigate and prosecute Medicaid fraud by passing State False Claims Acts modeled after the federal False Claims Act. *See* 42 U.S.C. § 1396h(a) (providing for a 10 percent increase in the states' share of Medicaid recoveries for states that enact False Claims Acts).

Courts in other similar and related cases have recognized the right of the United States and the states to share discovery and have entered protective orders which allow for such an exchange.⁶ In fact, a protective order entered by a court in the state of Texas contains a similar sharing provision and applies to Defendant Abbott.⁷ Ex. 5, ¶ 3(f). Such a sharing provision is entirely consistent with the purpose of a protective order, which is to prevent Abbott's competitors from obtaining certain confidential or trade secret information. In addition, under the terms of the proposed Protective Order, state law enforcement personnel, as defined under the proposed order must execute a confidentiality certification. Ex. 1, ¶ 13(j). Therefore, the proposed Protective Order allows the continued sharing of such information between the United States and the states but ensures that Abbott's confidential information remains protected from competitors.

Consistent with Rule 1 of the Federal Rules of Civil Procedure, providing for the "just, speedy, and inexpensive determination of every action," the United States' sharing of discovery with the states would save time and money and impose less of a burden on the parties involved, including many states that have limited resources. In investigating and prosecuting essentially

⁶For example, protective orders entered in two state courts allow the State of Florida and the State of Texas to share discovery with the United States and other states. *See* Ex. 2, ¶ 8, a protective order entered Aug. 19, 2004 between the State of Florida and Boehringer Ingelheim Corp. *et al.*; and Ex. 3, ¶ 3(f), a protective order entered November 23, 2004 between the State of Texas and Roxane Laboratories Inc. *et al.*; Ex. 4, ¶ 4(e), an amended protective order entered April 27, 2005 between the State of Texas and Abbott Laboratories Inc. *et al.*; Ex. 5, ¶ 3(f), a second amended protective order entered April 19, 2004 between the State of Texas and Dey Inc. *et al.*.

⁷The United States has not obtained materials pursuant to the Texas protective order because it is not a party to it and has not agreed to its terms, some of which are objectionable.

the same claims of overcharging Medicaid through falsely inflated pricing, the states would not have to re-subpoena the already-conducted discovery. *See, e.g.*, Ex. 6, Transcript of Motion Hearing before Judge Smith on July 19, 2004, at 42 (in ruling that the State of Florida could share discovery with other law enforcement officials, including the federal and state governments, Judge Smith stated that “the information ought to be available to the government to share with other governmental agencies who have the right to get that same type of information as long as that attorney general or law enforcement agency will agree to the restrictions [in the protective order]”).

VI. A Protective Order Must Address the United States’ Disclosure Obligations and Unique Concerns Governing the Use of Confidential Documents

A. United States’ Disclosure Obligations

The United States has unique obligations and concerns that must be addressed by inclusion of certain provisions in a protective order. The AWP MDL Protective Order, not surprisingly, is silent with respect to certain of these concerns and obligations since the United States was not a party to the negotiations that led to that Protective Order (Dkt. No. 276). The United States has obligations to disclose information under certain circumstances to Congress, to other federal entities and to third parties pursuant to the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, and Federal Rule 45 subpoenas. Thus, we ask that the Court adopt paragraphs 16-18 of the proposed Protective Order, as expressly set forth below. Proposed Protective Order, Ex. 1, ¶¶ 16-18.

As a matter of public policy, the United States must be able to disclose to any agency or department of the United States, or any division of any such agency or department, protected

competitive material relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. A protective order cannot prevent or in any way limit or impair the use of any such protected competitive material by an agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. The United States has included language in the proposed Protective Order to accommodate this necessary policy. Proposed Protective Order, Ex.1 ¶ 16. No defendant will be prejudiced by this provision because the United States agrees to maintain the confidentiality of any protected information received, consistent with the terms of the Protective Order. *See* proposed Protective Order, Ex. 1, ¶ 16.

In addition, most formal Congressional entities have well-recognized subpoena power, and may also seek documents and information informally. To the extent that any Congressional entity requests the United States to provide any document or information that contains protected competitive information, the agency is obligated to provide the information. There is no prejudice to any defendant by this provision because the United States agrees to use reasonable efforts to notify the company of the Congressional entity's request. *See* proposed Protective Order, Ex. 1, ¶ 17. To the extent that other third parties, pursuant to FOIA, or a subpoena, request information that contains protected competitive material, the United States may be obligated under the law to produce such information. However, the United States has included a provision in the proposed Protective Order to take reasonable steps to provide notice, allowable under the law, to the party whose information is protected. *See* proposed Protective Order, Ex.1, ¶ 18.

For these reasons, the United States asks the Court to adopt its proposed Protective Order including provisions found in paragraphs 16-18, Ex. 1.

B. United States' Access To and Use of a Defendant's Documents

The United States has concerns with respect to its ability to access and use documents produced by Abbott in state court litigation and investigations. The identical concerns are also applicable to any other defendants who may later join this AWP MDL in cases in which the United States is a party. In working with states with active AWP investigations it has already become apparent that Abbott's over-designation of confidential documents has hindered our efforts at coordination. In addition, the protective orders entered in other jurisdictions are frequently overly restrictive, and the United States cannot agree to be bound by these provisions.

In order to address these concerns and still ensure that Abbott's competitors do not obtain confidential or trade secret information, we ask that the Court adopt ¶ 2 of the proposed Protective Order, which allows Abbott the ability to not have to reproduce any documents previously produced in another investigation or action so long as they are deemed produced under the terms of the proposed Protective Order.

CONCLUSION

The United States' proposed Protective Order strikes the fair balance between access and use by the United States, and protection from disclosure of certain confidential and trade secret information to competitors. For these reasons, the United States asks the Court to enter its proposed Protective Order, and order that it be applicable to future cases to this AWP MDL where the United States is a party.

Respectfully Submitted,

For the United States of America,

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CERTIFICATION

The undersigned counsel certifies pursuant to LR 7.1(a)(2) that she and the Relator's counsel, James J. Breen, have conferred with counsel for the Defendant Abbott Laboratories, Inc. on the issues raised in this motion and have not been able to reach agreement.

Dated: September 15, 2006

/s/ Renée Brooker
Renée Brooker

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' AND RELATOR'S MEMORANDUM IN SUPPORT OF THEIR MOTION FOR A PROTECTIVE ORDER** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: September 15, 2006

/s/ Renée Brooker
Renée Brooker